Special 510(k): Device Modification
Cordis AVIATOR PLUS PTA Balloon Dilatation Catheter

Attachment 5: 510(k) Summary

MAY 16 2007

Submitter & Contact person:

Harm Hovinga
Senior Regulatory Affairs Associate
Cordis Europa, N.V.
Oosteinde 8
9301 LJ Roden
Netherlands

Date Prepared April 26, 2007

Trade Name Cordis **AVIATOR PLUS** Percutaneous Transluminal Angioplasty Balloon Dilatation Catheter

Classification Name and Device Classification

Classification Name:	Percutaneous Catheter (21 CFR 870.1250)
Classification:	Class II
FDA Classification Panel:	Cardiovascular
Product Code:	LIT

Predicate Device(s) The predicate device in this submission is the **Cordis AMIIA** PTA Balloon Dilatation Catheter (510(k) #K063563 & #K050645), which was determined substantial equivalent on March 7, 2007 and April 1, 2005 respectively.

Device description The Cordis **AVIATOR PLUS** PTA Balloon Dilatation Catheter is a catheter with a distal balloon and utilizes a rapid exchange design and accepts a 0.014" guide wire. The catheter tip is tapered to facilitate crossing of tight lesions. The proximal hub is used as a balloon inflation port. Two radiopaque marker bands within the balloon indicate the dilating section of the balloon and aid in balloon placement.

Special 510(k): Device Modification
Cordis AVIATOR PLUS PTA Balloon Dilatation Catheter

Intended Use	The Cordis **AVIATOR PLUS** PTA Balloon Dilatation Catheter is intended for Percutaneous Transluminal Angioplasty in the peripheral vasculature, including iliac, femoral, ilio-femoral, popliteal, infra popliteal, renal, and carotid arteries and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. This device is also indicated for post-dilatation of balloon-expandable and self-expanding stents in the peripheral vasculature.
Safety and Performance Data	The safety and effectiveness of the subject Cordis **AVIATOR PLUS** PTA Balloon Catheter has been demonstrated via data collected from non-clinical design verification and design validation tests and analyses.
Substantial Equivalence Conclusion	In summary, the subject Cordis **AVIATOR PLUS** PTA Catheter is substantial equivalent to the predecessor / predicate Cordis **AMIIA** PTA Balloon Dilatation Catheter.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 16 2007

Cordis Europa, N.V.
c/o Mr. Harn Hovinga
Senior Regulatory Affairs Associate
Oosteinde 8
9301 LJ Roden,
Netherlands

Re: K071189
Trade/Device Name: Aviator Plus PTA Balloon Dilatation Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II (Two)
Product Code: LIT
Dated: April 26, 2007
Received: April 30, 2007

Dear Mr. Hovinga:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donna R. Lochner

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Special 510(k): Device Modification
Cordis AVIATOR PLUS PTA Balloon Dilatation Catheter

Attachment 3

Intended Use Statement

510(k) Number (if known): K071189

Device Name: **Cordis AVIATOR PLUS Percutaneous Transluminal Angioplasty Balloon Dilatation Catheter**

Indications for Use Statement

The Cordis **AVIATOR PLUS** PTA Balloon Dilatation catheter is indicated for Percutaneous Transluminal Angioplasty in the peripheral vasculature, including iliac, femoral, ilio-femoral, popliteal, infra popliteal, renal, and carotid arteries and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. This device is also indicated for post-dilatation of balloon-expandable and self-expanding stents in the peripheral vasculature.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Diana R. Lechner
(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K071189